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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,405	05/08/2006	Andrew Chantry	056222-5080-US	3452

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EXAMINER	
YOUNG, HUGH PARKER	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/542,405	CHANTRY ET AL.	
	Examiner	Art Unit	
	Hugh P. Young	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the first Office action on application 10,542,405. There are twenty claims pending, all of which are subject to this restriction requirement.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 - 16, drawn to a pharmaceutical composition comprising a peptide that inhibits the interaction between Smad and UCH polypeptides.

Group II, claim(s) 1, 6 - 16, drawn to a pharmaceutical composition comprising a polyneucleotide construct of a peptide that inhibits the interaction between Smad and UCH polypeptides.

Group III, claim(s) 17 and 18, drawn to methods of treating diseases using a pharmaceutical composition comprising a polyneucleotide construct of a peptide for inhibiting the interaction between Smad and UCH polypeptides.

Group IV, claim(s) 19 and 20, drawn to methods screening candidate compounds for that inhibit the interaction between Smad and UCH polypeptides.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: polypeptides that inhibit Smad3 are disclosed by Germain et al. in PCT/GB00/03265 (WO01/14413 A2), teaching polypeptides that bind with and interfere with Smad3 on page 7, lines 14-26

and page 8, lines 1 and 2.

The above-described groups appear to have a general inventive concept of molecules that prevent, inhibit or reduce the association of a Smad protein with a UCH or XNA construct. The above-cited reference, however, teaches polypeptides that interfere with Smad3 by binding with it. The lack of unity is based on applying the prior art records that would be or are encompassed under the composition in the instant claims 1-5. Because this prior art reference teaches Smad-binding molecules (peptides) that creates the general inventive concept, and because the molecules of Groups I – III are not a contribution over the art, there is no general inventive concept due to the lack of the same or corresponding special technical feature.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: antibodies that bind with Smad3 are disclosed by Xu et al. (2002) in *Biology of Reproduction* vol. 66, pages 1571-1578, as shown in photographs of an fluorescent antibody binding assay in Figure 3, page1574.

The above-described groups appear to have a general inventive concept of molecules that prevent, inhibit or reduce the association of a Smad protein with a UCH or XNA construct. The above-cited reference, however, teaches antibodies that bind with segments of Smad3. The lack of unity is based on applying the prior art records that would be or are encompassed under the composition in the instant claims 1-5. Because this prior art reference teaches Smad-binding molecules (antibodies) that

creates the general inventive concept, and because the molecules of Groups I – III are not a contribution over the art, there is no general inventive concept due to the lack of the same or corresponding special technical feature.

3. Claims 1 -16 comprise peptides that differ in structure because the polypeptide binding sites provided in these claims comprise non-conservative amino acid substitutions. Thus, overlapping sequences have been selected for inventions I – II and the peptide binding sites in each of inventions I – II are considered to be patentably distinct. If any one of inventions I – II is elected, the elected invention will be examined insofar as it pertains to a specifically disclosed binding site target on **either** a Smad (a UCH-binding site) **or** on a UCH (a Smad-binding site). This is not a species election. If sequences of the other five inventions happen to be found in the search of the selected invention, the examiner will rejoin the invention comprising the found sequence in accordance with *in re Ochiai.* Rejoinder is possible if Applicants provide a single and specific representative subsequence and state that the sequences are **not patentably distinct,** given a disclosed unifying common feature. Applicants are informed that if their specified sequence is found that all or a specified subset of sequences are obvious over that prior art sequence.

4. Claims 6, 13 and 14 comprise peptides that differ in structure because the contiguous portions of Smad peptide claimed comprise non-conservative amino acid substitutions. Thus, overlapping sequences have been selected for inventions I and II and the peptide binding sites in each of inventions I and II are considered to be

patentably distinct. If any one of inventions I or II is elected, the elected invention will be examined insofar as it pertains to a specifically disclosed contiguous portion of a Smad polypeptide. This is not a species election. If sequences of the other five inventions happen to be found in the search of the selected invention, the examiner will rejoin the invention comprising the found sequence in accordance with *in re Ochiai.* Rejoinder is possible if Applicants provide a single and specific representative subsequence and state that the sequences are **not patentably distinct,** given a disclosed unifying common feature. Applicants are informed that if their specified sequence is found that all or a specified subset of sequences are obvious over that prior art sequence.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventorship

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hugh P. Young whose telephone number is (571)-272-4988. The examiner can normally be reached on 8:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hugh P. Young Ph.D. GAU 1654

JON WEBER
SUPERVISORY PATENT EXAMINER